REMARKS

Claims 1, 2, 4, 5, 7, 9 and 10 are pending in this application. Claim 5 has been amended.

Applicants, by canceling or amending any claims, make no admission as to the validity of any rejection made by the Examiner against any such claims. Applicants reserve the right to reassert any of the claims canceled and/or the original claim scope of any claim amended, in a continuing application.

Claim 5 has been amended to recite "[a] mammalian liver cell obtained by excising the immortalizing gene from a reversibly immortalized mammalian liver cell line or a passage cell line thereof of Claim 1, wherein a reversibly immortalized mammalian liver cell line or a passage cell line thereof contains an immortalizing gene interposed between a pair of site-specific recombination sequences and a suicide gene in the outside of the pair of site-specific recombination sequences, wherein the suicide gene can exhibit its function after excision of the pair of site-specific recombination sequences, wherein the liver cell line or a passage cell line thereof does not contain a promoter derived from virus." Support for this amendment can be found throughout the specification and claims as filed.

No new matter is introduced to this application within the meaning of 35 USC §132.

In view of the following, further and favorable consideration is respectfully requested.

I. Entry of Amendment to Specification.

Applicants respectfully request that the Examiner reconsider and enter the amendment to the specification filed on April 9, 2010 in the captioned application as the amendment merely corrects an obvious oversight.

In particular, as known by those skilled in the art at the time of filing of the instant application, a CMV promoter is a ***viral*** promoter. As evidence of this, Applicants submit herewith "Reference document 1," page 11254, abstract: R. L. Smith, D. L. Traul, et al., Journal of Virology, 74(23), 11254-11261(2000). Based on Reference document 1, it is clear that CMV promoter had been listed as non-viral promoter in the original specification by mistake.

Therefore, Applicants submit that amendment to the specification is for the correction of the clerical error, and does not constitute new matter. Accordingly, Applicants request reconsideration and entry of the amendment to the specification.

II. Rejection of Claims 5 and 10 under 35 U.S.C. §112, 2nd paragraph

Claims 5 and 10 are rejected under 35 U.S.C. §112, 2nd paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner asserts that claim 5 is indefinite \the cell of claim 5 is allegedly structurally or functionally broader than the cell of claim 1. Claim 10 is rejected since it depends from claim 5.

In view of the following this rejection is respectfully traversed.

Applicants submit that claim 5 has been amended herein to recite additional structural elements. The amendments to claim 5 render the scope of claim 5 more limited than the scope of claim 1. Therefore, claims 5 and 10 are not indefinite.

In view of the foregoing, Applicants respectfully submit that the present claims are clear and definite. Accordingly, Applicants respectfully request that the Examiner

reconsider and withdraw this rejection.

III. Rejection of Claims 1, 2, 5, 7 and 10 under 35 U.S.C. §102(b)

Claims 1, 2, 5, 7 and 10 remain rejected as being anticipated by by Westerman (PNAS, Aug. 1996, Vol. 93, pg 8971-8976), Salmon (Molecular Therapy, Oct. 2000, Vol. 2, No.4, pg 404-414), Kobayashi (Science, Feb. 18,2000, Vol. 287, pg 1258-1262), Kobayashi (Human Cell., March 2000, Vol. 13, No.1, pg 7-13), Kobayashi (Saisei Iryo, Nov. 2002, Vol. 1, No.2, pg 23-28) and Kobayashi (Cell Technology, June 2000, Vol. 19, No.6, pg 864-868) for the reasons set forth in the Official Action.

In view of the following, Applicants respectfully traverse this rejection.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

Claim 1, recites "A reversibly immortalized mammalian liver cell line or a passage cell line thereof, containing an immortalizing gene interposed between a pair of site-specific recombination sequences and a suicide gene in the outside of the pair of site-specific recombination sequences, wherein the suicide gene can exhibit its function after excision of the pair of site-specific recombination sequences, wherein the liver cell line or a passage cell line thereof does not contain a promoter derived from virus." Specifically, the liver cell

line or a passage cell line thereof ***does not contain a promoter derived from virus***.

Applicants respectfully submit the instant claims are distinguishable from the teachings of all the cited references. All of the promoters described in the cited references are ***promoters derived from virus***, such as a CMV promoter and viral LTR.

In contrast, the presently pending claims recite the liver cell line or the passage cell line thereof ***does not contain a promoter derived from virus***. Therefore, the cited references, which all teach a promoter derived from a virus, do not teach each and every element of the presently pending claims and do not anticipate the presently pending claims.

From the outset, Applicants respectfully submit that, as recoginized by those skilled in the art:

a) CMV promoter is a viral promoter;

b) Viral LTR (long terminal repeat) corresponds to a viral promoter;

c) SV40T gene does not contain a promoter (*see* the below point (5)); and

d) In Example of the present specificaion CAG promoter, which is non-viral, is utilized.

With regard to the cited references, Applicants note that the promoters described therein are as follows:

(1) viral LTR and CMV promoters are described by Westerman (PNAS, Aug. 1996, Vol. 93, p.8971-8976);

(2) CMV promoters are described by Salmon (MolecularTherapy, Oct. 2000, Vol. 2, No. 4, p.404-414);

(3) MoMLV (Moloney murine leukemia virus) LTR promoters are described by Kobayashi (Science, Feb. 18, 2000 Vol. 287, p.1258-1262),

(4) MoMLV LTR promoters are described by Kobayashi (Human Cell., March 2000, Vol. 13, No.1, p.7-13);

(5) LTR and CMV promoters are described by Kobayashi (Saisei Iryo, Nov. 2002, Vol. 1, No. 2, p. 23-28); and

(6) MoMLV LTR promoters are described by Kobayashi (Cell Technology, June 2000, Vol. 19, No. 6, p. 864-868).

Applicants respectfully submit that none of the cited references describe reversibly immortalized mammalian liver cell without a viral promoter, as recited in the present claims. Accordingly, the presently pending claims are novel and non-obvious.

For at least the foregoing reasons, the cited references do not anticipate presently pending claims 1-5, 7 and 10 within the meaning of 35 USC § 102(b). Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

With regard to the SV40T gene, the Examiner asserts that the SV40T gene is a viral gene comprising a viral promoter. *See* page 6 of the Official Action. Applicants respectfully disagree with the Examiner's position.

In particular, as described on page 10, lines 10 and 11 of the present specification, the SV40T gene is a known tumor antigen (T antigen) gene of DNA type tumor virus, simian virus 40 large T antigen gene. Applicants submit that at the time filing the present application, skilled artisans understood that SV40T gene is a gene and does not include any promoter. As evidence of this, Applicants submit herewith a copy of both "reference document 2," i.e., JP07079773A, and "reference document 3," i.e., WO 01/78757A2 (corresponding US Patent Application Publication No. 2010/047218A1)) . As shown at paragraphs 0006 and 0007 of reference document 2, and Figure 1 of reference document

3, SV40T gene is a gene and does not include any promoter

In addition, Applicants respectfully request clarification of the Examiner's assertion that the description on page 23, lines 16 to 27 indicates that SV40T gene. In this regard, Applicants note that the cited section provides that:

> Gene expression in CYNK-1 cell (deposited with International Patent Organism Depository, National Institute of Advanced Industrial Science and Technology, address: AIST Tsukuba Central 6, 1-1, Higashi 1-Chome, Tsukuba-shi, Ibaraki-ken, 305-8566 Japan, deposited date: March 10, 2004, accession number: FERM BP-08657) before and after excision of SV40T gene With respect to the CYNK-1 cell (deposited with International Patent Organism Depository, National Institute of Advanced Industrial Science and Technology, address: AIST Tsukuba Central 6, 1-1, Higashi 1-Chome, Tsukuba-shi, Ibaraki-ken, 305-8566 Japan, deposited date: March 10, 2004, accession number: FERM BP-08657) before and after excision of SV40T gene, the expression of...

Applicants note that it appears the Examiner intends to point out the cell in FERM BP-08657. However, as mentioned previously, the cell line FERM BP-08657 differs from the cell lines in all of the cited references.

In view of the foregoing, Applicants submit the presently claimed subject matter is novel. Therefore, reconsideration and withdrawal of this rejection is respectfully submitted.

CONCLUSION

In view of the foregoing, Applicants submit the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP

Date: September 27, 2010

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